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PATENT

## In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Nancy Auestad, et al.	EXAMINER: Not yet assigned
SERIAL NO.: 10/576,522	ART UNIT: Not yet assigned
FILING DATE: April 19, 2006	DOCKET NO.: 7278US01
TITLE: <b>METHOD OF INCREASING LEAN BODY MASS AND REDUCING BODY FAT MASS IN INFANTS</b>	
I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below.	
<u>Wendy Detwiler 8-4-06</u> Wendy Detwiler Date	

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- A copy of each cited reference is provided;
- Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- No fee is due because:
- This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).

If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025. A duplicate sheet of this page is enclosed.

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Respectfully submitted,

  
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Sheet 1 of 5

FOBM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 7278US01	Serial No. 10/576,522
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Auestad, et al.	
(Use several sheets if necessary)		Filing Date April 19, 2006	Group Not yet assigned.

#### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

#### FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

#### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Carlson SE, Neuringer M. "Polyunsaturated fatty acid status and neurodevelopment: a summary and critical analysis of the literature." <i>Lipids</i> 1999; 34: 171-78
		Innis SM. "The role of dietary n-6 and n-fatty acids in developing brain." <i>Develop Neurosci</i> 2000; 22: 474-80.
		O'Connor DL, Hall R, Adamkin D, Auestad N, Castillo M, Connor WE, et al. "Growth and development in preterm infants fed long-chain polyunsaturated fatty acids: a prospective, randomized controlled trial." <i>Pediatrics</i> 2001; 108: 359-71.
		SanGiovanni JP, Berkey CS, Dwyer JT, Colditz GA. "Dietary essential fatty acids, long-chain polyunsaturated fatty acids, and visual resolution acuity in healthy fullterm infants: a systematic review." <i>Early Hum Dev</i> 2000; 57:165-88.
		Innis SM, Adamkin DH, Hall RT, Kalhan SC, Lair C, Lim M, et al. "Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in preterm infants fed formula." <i>J Pediatr</i> 2002; 140:547-54.
		Martinez FE, Sieber VM, Jorge SM, Ferlin ML, Mussi-Pinhata MM. "Effect of supplementation of preterm formula with long chain polyunsaturated fatty acids on mineral balance in preterm infants." <i>J Pediatr Gastroenterol Nutr</i> 2002; 35:503-7.
		Vanderhoof J, Gross S, Hegyi T. "A multicenter long-term safety and efficacy trial of preterm formula supplemented with long-chain polyunsaturated fatty acids." <i>J Pediatr Gastroenterol Nutr</i> 2000;31:121-27.
		Fewtrell MS, Morley R, Abbott RA, Singhal A, Isaacs EB, Stephenson T, et al. "Double-blind, randomized trial of long-chain polyunsaturated fatty acid supplementation in formula fed to preterm infants. <i>Pediatrics</i> 2002;110:73-82.
		Watkins BA, Lippman HE, Le Bouteiller L, Li Y, Seifert MF. "Bioactive fatty acids: role in bone biology and bone cell function." <i>Prog Lipid Res</i> 2001; 40:125-48.
		Peyron-Case E, Quignard-Boulange A, Laromiguere M, Feing-Kwong-Chan S, Veronese A, Arduouin B, et al. Dietary fish oil increases lipid mobilization but does not decrease lipid storage-related enzyme activities in adipose tissue of insulin-resistant, sucrose-fed rats. <i>J. Nutr</i> 2003;133:2239-43.
		Raclot T, Groscolas R, Langin D, Ferre P. "Site-specific regulation of gene expression by n-3 polyunsaturated fatty acids in rat white adipose tissues. <i>J Lipid Res</i> 1997; 38:1963-72
		Raisz LG. "Bone cell biology: new approaches and unanswered questions." <i>J Bone Miner Res</i> 1993;8:S457-65

EXAMINER

DATE CONSIDERED

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 5

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**U.S. PATENT DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

		Watkins BA, Li Y, Lippman HE, Feng S. "Modulatory effect of omega-3 polyunsaturated fatty acids on osteoblast function and bone metabolism." Prostaglandins Leukot Essent Fatty Acids 2003;68:387-98.
		Association for Official Agricultural Chemists. Official Methods of Analysis. In. 14 <sup>th</sup> ed. Arlington, VA: Association for Official Agricultural Chemists; 1984;28.082-28.085.
		Carver JD, Wu PY, Hall RT, Ziegler EE, Sosa R, Jacobs J, et al. "Growth of preterm infants fed nutrient-enriched or term formula after hospital discharge." Pediatrics 2001; 107:683-89.
		Cooke RJ, Embleton ND, Griffin IJ, Wells JC, McCormick KP. "Feeding preterm infants after hospital discharge: growth and development at 18 months of age." Pediatr Res 2001;49:719-22.
		Lucas A, Fewtrell MS, Morley R, Singhal A, Abbott RA, Isaacs E, et al. Randomized trial of nutrient-enriched formula versus standard formula for postdischarge preterm infants." Pediatrics 2001;108:703-11.
		Worrell LA, Thorp JW, Tucker R, McKinley LT, Chen J, Chng YM, et al. The effects of the introduction of a high-nutrient transitional formula on growth and development of very-low birth-weight infants." J Perinatol 2002;22:112-19.
		Rajaram S, Carlson SE, Koo WW, Braselton WE. "Plasma mineral concentrations in preterm infants fed a nutrient-enriched formula after hospital discharge." J Pediatr 1995;126:791-96.
		Bishop NJ, King FJ, Lucas A. "Increased bone mineral content of preterm infants fed with a nutrient enriched formula after discharge from hospital." Arch Dis Child 1993;68:573-78.
		Brunton JA, Saigal S, Atkinson SA. "Growth and body composition in infants with bronchopulmonary dysplasia up to 3 months corrected age: a randomized trial of a high-energy nutrient-enriched formula fed after hospital discharge." J Pediatr 1998;133:340-45.
		Chan GM. "Growth and bone mineral status of discharged very low birth weight infants fed different formulas or human milk." J. Pediatr 1993;123:439-43.
		Cooke RJ, McCormick K, Griffin IJ, Embleton N, Faulkner K, Wells JC, et al. "Feeding preterm infants after hospital discharge: effect of diet on body composition." Pediatr Res 1999;46:461-64.

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		DeCurtis M, Pieltain C, Rigo J. "Body composition in preterm infants fed standard term or enriched formula after hospital discharge." Eur J Nutr 2002;41:177-82.
		Carlson SE, Cooke RJ, Werkman SH, Tolley EA. "First year growth of preterm infants fed standard compared to marine oil n-3 supplemented formula." Lipids 1992;27:901-7.
		Carlson SE, Werkman SH, Tolley EA. "Effect of long-chain n-3 fatty acid supplementation on visual acuity and growth of preterm infants with and without bronchopulmonary dysplasia." Am J. Clin Nutr 1996;63:687-97.
		Ryan AS, Montaldo MB, Groh-Wargo S, Mimouni F, Sentipal-Walerius J, Doyle J, et al. "Effect of DHA-containing formula on growth of preterm infants to 59 weeks postmenstrual age." Am J Human Biol 1999;11:457-67.
		Clandinin MT, Van Aerde JE, Parrott A, Field CJ, Euler AR, Lien EL. "Assessment of the efficacious dose of arachidonic and docosahexaenoic acids in preterm infant formulas: fatty acid composition of erythrocyte membrane lipids." Pediatr Res 1997;42:819-25.
		Faldera G, Govoni M, Alexxandroni R, Marchiani E, Salvioli GP, Biagi PL, et al. "Visual evoked potentials and dietary long chain polyunsaturated fatty acids in preterm infants." Arch Dis Child Fetal Neonatal Ed 1996;75:F108-12.
		Uauy R, Hoffman DR, Birch EE, Birch DG, Jameson DM, Tyson J. "Safety and efficacy of omega-3 fatty acids in the nutrition of very low birth weight infants: soy oil and marine oil supplementation of formula." J Pediatr 1994;124:612-20.
		Vanderhoof J, Gross S, Hegyi T, Clandinin T, Porcelli P, DeCristofaro J, et al. "Evaluation of a long-chain polyunsaturated fatty acid supplemented formula on growth, tolerance and plasma lipids in preterm infants up to 48 weeks postconceptional age." J Pediatr Gastroenterol Nutr 1999;318-26
		Wuben IP, Atkinson SA, Shah JK, Paes B. "Growth and body composition of preterm infants: Influence of nutrient fortification of mother's milk in hospital and breastfeeding post-hospital discharge. Acta Paediatr 1998;87:780-85.
		Schmelze HR, Fusch C. "Body fat in neonates and young infants: validation of skinfold thickness versus dual-energy Z-ray absorptiometry." Am J. Clin Nutr 2002;76:1096-00.
		Raclot T, Oudart H. "Selectivity of fatty acids on lipid metabolism and gene expression." Proc Nutr Soc 1999;58:633-46.
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Sheet 4 of 5

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	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

		Hill JO, Peters JC, Lin D, Yakubu F, Greene J, Swift L. "Lipid accumulation and body fat distribution is influenced by type of dietary fat fed to rats." <i>Int J Obes Relat Metab Disord</i> . 1993; 17:223-36.
		Parrish CC, Pathy DA, Angel A. "Dietary fish oils limit adipose tissue hypertrophy in rats." <i>Metabolism</i> 1990;30:217-19.
		Petersen RK, Jorgensen C, Rustan AC, Froyland L, Muller-Decker K, Furstenberger G, et al. "Arachidonic acid -dependent inhibition of adipocyte differentiation requires PKA activity and is associated with sustained expression of cyclooxygenases. <i>J Lipid Res</i> 2003;16.
		Benhizia F, Hainault I, Serougne C, Lagrange D, Hajduch E, Guichard C, et al. "Effects of a fish oil-lard diet on rat plasma lipoproteins, liver FAS, and lipolytic enzymes." <i>Am J Physiol</i> 1994;267:E975-82
		Halvorsen B, Rustan AC, Madsen L, Reseland J, Berge RK, Sletnes P, et al. "Effects of long-chain monounsaturated and n-3 fatty acids on fatty acid oxidation and lipid composition in rats." <i>Ann Nutr Metab</i> 2001;45:30-7.
		Rustan AC, Hustvedt BE, Drevon CA. "Postprandial decrease in plasma unesterified fatty acids during n-3 fatty acid feeding is not caused by accumulation of fatty acids in adipose tissue." <i>Biochim Biophys Acta</i> 1998;1390:245-57
		Peyron-Case E, Taverna M, Guerre-Millo M, Veronese A, Pacher N, Slama G, et al. "Dietary (n-3) polyunsaturated fatty acids up-regulate plasma leptin in insulin-resistant rats." <i>J Nutr</i> 2002;132:2235-40.
		Lapillonne A, Braillon P, Claris O, Chatelain PG, Delmas PD, Salle BL. "Body composition in appropriate and in small for gestational age infants." <i>Acta Paediatr</i> 1997;86:196-00
		Hediger ML, Overpek MD, Kuczmarski RJ, McGlynn A, Maurer KR, Davis WW. "Muscularity and fatness of infants and young children born small- or large-for-gestational-age." <i>Pediatrics</i> 1998;102:E60.
		Barker DJ. "Intrauterine programming of coronary heart disease and stroke." <i>Acta Paediatr Suppl</i> 1997;423:178-82.
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		Barker DJ. "The fetal origins of coronary heart disease." <i>Acta Paediatr Suppl</i> 1997;422:78-82.
		Phipps K, Barker DJ, Hales CN, Fall CH, Osmond C, Clark PM. "Fetal growth and impaired glucose tolerance in men and women." <i>Diabetologia</i> 1993;36:225-28.
		Ehrenkraza RA, Younes N, Lemons JA, Fanaroff AA, Donovan EF, Wright LL, et al. "Longitudinal growth of hospitalized very low birth weight infants." <i>Pediatrics</i> 1999;104:280-89.
		Koo WW, Hammami M, Margeson DP, Nwaesei C, Montalto MB, Lasekan JB. "Reduced bone mineralization in infants fed palm olein-containing formula: a randomized, double-blinded, prospective trial." <i>Pediatrics</i> 2003;111:1017-23.
		Watkins BA, Li Y, Allen KG, Hoffmann WE, Seifert MF. "Dietary ratio of (n-6)/(n-3) polyunsaturated fatty acids alters the fatty acid composition of bone compartments and biomarkers of bone formation in rats." <i>J Nutr</i> 2000;130:2274-84.
		Lucia VD, Fitzpatrick-Wong SC, Weiler HA. "Dietary arachidonic acid suppresses bone turnover in contrast to low dosage exogenous prostaglandin E(2) that elevates bone formation in the piglet." <i>Prostaglandins Leukot Essent Fatty Acids</i> 2003;68:407-13.
		Weiler H. "Dietary supplementation of arachidonic acid is associated with higher whole body weight and bone mineral density in growing pigs." <i>Pediatr Res</i> 2000;47:692-97.
		Watkins BA, Shen CL, Allen KG, Seifert MF. "Dietary (n-3) and (n-6) polyunsaturates and acetylsalicylic acid alter ex vivo PGE2 biosynthesis, tissue IGF-I levels, and bone morphometry in chicks." <i>J Bone Miner Res</i> 1996;11:1321-32.
		Watkins BA, Shen CL, McMurtry JP, Xu H, Bain SD, Allen KG, et al. "Dietary lipids modulate bone prostaglandin E2 production, insulin-like growth factor-I concentration and formation rate in chicks." <i>J Nutr</i> 1997;127:1084-91.
		Weiler HA, Fitzpatrick-Wong S. "Dietary long-chain polyunsaturated fatty acids minimize dexamethasone-induced reductions in arachidonic acid status but not bone mineral content in piglets." <i>Pediatr Res</i> 2002;51:282-89.
		Rigo J, De Curtis M, Pieltain C, Picaud JC, Salle BL, Senterre J. "Bone mineral metabolism in the micropremie." <i>Clin Perinatol</i> 2000;27:147-70.
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